

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 29 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Registration of UICK-2 (EPA Symbol No. 4822-LNO), Containing 10% p-Menthane-3,8-Diol (Chemical No. 011550) as its Active Ingredient. Review of Product Chemistry and Efficacy Studies (MRIDs 446421-08, -09, and -10); Case No. 062676, Submission No. 555602; DP Barcode 252712.

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: James Downing, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

S. C. Johnson & Son, Inc. requests registration of UICK 2 (EPA Symbol No. 71038-G), containing 10% p-menthane-3, 8-diol as its active ingredient. The end-use product is intended for use as repellent on human skin. In support of the registration,

BPB's CONCLUSIONS AND RECOMMENDATIONS

1. BPB does not support the registration of UICK-2 (EPA Symbol No. 71038-G) due to deficiencies in product chemistry data, the CSF, product performance (efficacy) studies, and the proposed label.
2. Product chemistry studies submitted for the manufacturing process of the end-use product (151-11), discussion of the formation of impurities in the end-use product (151-12), certified ingredient limits (151-15), analytical method (151-16), and physical/chemical properties (151-17) are acceptable. No additional data are required for these guideline requirements. Preliminary analysis data are not required for the end-use product because it is manufactured via a simple mixing process.

3. The product identity and composition (151-10) data are unacceptable. The percentages by weight of the TGAI and the a.i. listed on the CSF (dated 8/18/98) indicate that the TGAI contains 10% p-menthane-3, 8-diol as its active ingredient. However, the MSD sheet shows that the TGAI contains 93.8% p-menthane-3, 8-diol. This discrepancy must be resolved. Additionally, limits of detection data must be reported for the analytical method (151-16).
4. Since the TGAI (Granola 97) is not an EPA registered product, the following studies must be submitted for the TGAI: manufacturing process (151-11); discussion of the formation of impurities (151-12); preliminary analysis (151-13); certified ingredient limits (151-15); analytical method (151-16; if different from the method reported for the end-use product); and physical/chemical properties (151-17). The registrant has the option of submitting this information to the Agency for review, or requesting that the manufacturer/supplier of the TGAI submit this information directly to the Agency.
5. The CSF (dated 8/18/98) is unacceptable and a revised CSF must be submitted. The revised CSF must show the percentage of active ingredient in the TGAI (Section 10 of the CSF) and list the name and address of the supplier of one inert ingredient in place of the word "commodity" (Section 11 of the CSF).
6. The submitted product performance (efficacy) studies for black flies (*Simulium* spp.) and biting gnats (*Culicoides* spp.) are supplemental and do not support registration of the end-use product. To upgrade the product performance studies to acceptable, the registrant must submit one additional field test for black flies and one additional field test for biting gnats. No additional field studies are required for mosquitoes (*Aedes* spp. and *Mansonia* spp.).
- 7a. The proposed product label is unacceptable. A revised label must be submitted. Label claims regarding the length of time the product repels biting flies and biting gnats cannot be assessed for accuracy until the requirement for additional field testing is satisfied (see Conclusion 5 above). Data contained in the submitted studies indicate repellency of up to 5 hours for black flies and up to 2 hours for sand gnats. A label claim for two hours repellency against mosquitoes is acceptable. Label statements indicating that the product repels insects and/or bugs are too broad. The registrant must only list those insect species for which acceptable product performance studies have been submitted (see Conclusion 5 above).
- 7b. There are numerous product claims on the front panel that are redundant and/or overlapping; these statements must be edited for accuracy and clarity. Statements indicating that the product repels "naturally" should be removed. Due to the volatile nature of the end-use product (flammability flash point 13.8°C), the product label must indicate that the product is flammable.

8. Data requirements for acute toxicity (152-10 to -17) were not addressed in this review. Ecotoxicity/nontarget organism studies (154-6 to -15 and 155-4 to -13) are not required because the end-use product is an insect repellent applied to human skin.

STUDY SUMMARIES

Product Chemistry

The product identity and disclosure of ingredients, manufacturing process for the end-use product, a discussion of the formation of impurities (end-use product), certified ingredient limits, analytical methods, and physical/chemical properties for UICK-2 were presented (MRIDs 446421-08 and -09). The end-use product consists of one basic formulation. The active ingredient is p-menthane-3, 8-diol which comprises 10% of the product; it is added to the end-use product in the TGAI (Granola 97) which contains 995 a.i. by weight. The TGAI is not currently registered by EPA; no manufacturing process data were submitted for the TGAI. The end-use product is manufactured via a simple mixing process with no chemical reactions. Therefore, no discussion of manufacturing impurities or preliminary analysis data are required. The submitted certified ingredient limits for the active and inert ingredients were acceptable. An analytical method was not submitted but none is required because the end-use product is produced via a simple mixing process. Acceptable physical/chemical properties were submitted.

Classification: Unacceptable; to upgrade the product chemistry studies to acceptable, the deficiencies identified in Conclusions 3, 4, and 5 above).

Product Performance (Efficacy)

Product performance studies were submitted in support of OPPTS 810.3400 [*Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments, EPA 712-C-98-419, March 1998*]. One field study each was submitted for black flies (*Simulium* spp.) and biting gnats (*Culicoides* spp.), and two field studies were submitted for mosquitoes (*Aedes* spp. and *Mansonia* spp.). Data contained in the submitted studies indicate repellency of up to 5 hours for black flies, up to 2 hours for sand gnats, and for up to 2 hours repellency against mosquitoes. The black fly test was conducted in MI, the sand gnat test was conducted in FL, and the two mosquito tests were respectively conducted in FL and WI. Current guidelines require five field tests for each species at geographically separate locations. New, proposed guidelines will specify that only two field trials are required. Based on the above information, the black fly and sand gnat tests are considered supplemental; to upgrade these studies to acceptable, one additional field test must be submitted for each species at a location that is geographically separated from the first tests. Therefore, label claims regarding the length of time the product repels biting flies and biting gnats cannot be assessed for accuracy until the requirement for additional field testing is satisfied. A label claim for up to two hours repellency against mosquitoes is acceptable.

Classification: Supplemental; to upgrade the studies to acceptable, the deficiencies identified in Conclusion 6 above must be resolved.

LABEL REVIEW

A proposed product label was submitted and reviewed. The product label is unacceptable. To upgrade the label to acceptable the deficiencies identified in Conclusions 7a and 7b above must be resolved.

cc: R. S. Jones, J. Downing, BPPD Subject File
R. S. Jones: F.T. CM2, 703/308-5071: 6/29/99

**THE FOLLOWING PAGES AND ATTACHMENTS CONTAIN CONFIDENTIAL
BUSINESS INFORMATION (CBI)**

DATA EVALUATION REPORT

UICK-2 (p-menthane 3,8 diol)
(Moeller Plus)

STUDY TYPES: Chemical and Physical Properties (OPPTS 830.6302-6304,
830.6313-6321, 830.7000-7950)

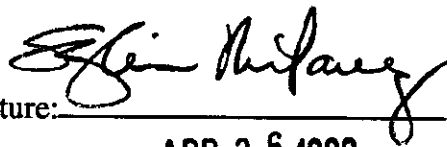
Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

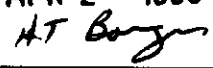
Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 26

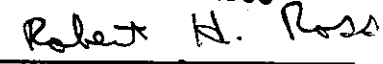
Primary Reviewer:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: 
Date: APR 26 1999

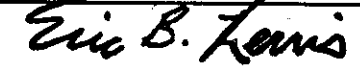
Robin A. Brothers, Ph.D., D.A.B.T.

Signature: 
Date: APR 26 1999

Robert H. Ross, M.S., Group Leader

Signature: 
Date: APR 26 1999

Quality Assurance:
Eric B. Lewis, M.S.

Signature: 
Date: APR 26 1999

Disclaimer

This Data Evaluation Report may have been altered by the BPPD subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

UICK-2
MRID 44642108

Chemical and Physical Properties (OPPTS 830.6302-6304,
830.6313-6321, 830.7000-7950)

EPA Reviewer: Russell S. Jones, Ph.D.

EPA Work Assignment Manager:

Sheryl K. Reilly, Ph.D.

Biopesticides & Pollution Prevention Division (7511W)

Russell S. Jones Date, 6/29/99

_____, Date, _____

DATA EVALUATION RECORD

STUDY TYPE: Chemical and Physical Properties (OPPTS 830.6302-6304, 830.6313-6321, 830.7000-7950)

DP BARCODE: D252712

SUBMISSION CODE: S555602

P.C. BARCODE: 011550

CASE: 062676

TEST MATERIAL (PURITY): UICK-2 (p-menthane 3,8 diol, 10% a.i. (formula number 15045R59-2))

SYNONYMS: Uick 2; Moeller Plus (from MRID 44642101)

CITATION: Welch, K.J. (1998) Physical and chemical characteristics for UICK-2. Formula number 15045R59-2. S.C. Johnson and Son, Inc., 1525 Howe Street, Racine, WI 53403-2236. Study no. 377A1, July 24, 1998. MRID 44642108. Unpublished.

SPONSOR: S.C. Johnson & Son, Inc., Product Safety, Toxicology and Environmental Assessment, Mail Station 122, 1525 Howe Street, Racine, Wisconsin 53403-2236.

EXECUTIVE SUMMARY: The color, physical state, odor, melting point, boiling point, density, solubility, vapor pressure, dissociation constant, octanol/water coefficient, pH, stability, oxidizing/reducing action, flammability, explodability, viscosity, miscibility, particle size, UV/visible absorption, and dielectric breakdown voltage of UICK-2 (formula number 15045R59-2) were addressed in MRID 44642108.

Classification of the studies - **Acceptable** for all performed analyses. The storage stability and corrosion characteristics will be reported in another study, completing the guideline requirements for Physical and Chemical Characteristics.

COMPLIANCE: Signed Data Confidentiality and GLP statements were provided; a minor deviation was noted in the GLP statement. A Quality Assurance statement was not included.

A. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302 - 830.7950)

Color (830.6302): clear, colorless

Physical State (830.6303): liquid

Odor (830.6304): ethanol-like

Particle size (830.7520): not required for end-use products

Melting Point (830.7200): not required for end-use products

Boiling Point (830.7220): not required for end-use products

Density (830.7300): 0.83 g/mL at 23°C

Solubility (830.7840): not required by EPA for end-use products

Vapor Pressure (830.7950): not required for end-use products

Dissociation Constant (830.7370): not required for end-use products

Octanol/Water Coefficient (830.7550; 830.7860): not required for end-use products

pH (830.7000): not performed because the product does not disperse in water

Stability (830.6313): not required for end-use products

UV/Visible Absorption (830.7050): not required for end-use products

Oxidizing/reducing action (830.6314): UICK-2 does not contain any oxidizing or reducing agents

Flammability (830.6315): the flash point was determined to be 13.8°C; ATSDM method D-56

Explodability (830.6316): product contains no explosive materials

Storage stability (830.6317): not performed - to be reported in a separate study

Viscosity (830.7100): 2.9 centipoise at 25°C

Miscibility (830.6319): Not applicable: the product is non-dilutable

Corrosion characteristics (830.6320): not performed - to be reported in a separate study

Dielectric breakdown voltage (830.6321): Not applicable; not intended for use around electrical equipment

B. DISCUSSION

MRID 44642108 examined numerous physical and chemical characteristics of UICK-2. Appropriately addressed parameters are color, physical state, odor, melting point, boiling point, density, solubility, vapor pressure, dissociation constant, octanol/water coefficient, pH, stability, oxidizing/reducing action, flammability, explodability, viscosity, miscibility, particle size, UV/visible absorption, and dielectric breakdown voltage. The storage stability and corrosion characteristics will be reported in another study, completing the guideline requirements for Physical and Chemical Characteristics.

Classification of the studies - **Acceptable** for all performed analyses.

C. STUDY DEFICIENCIES

A determination of the pH was not made because the product does not disperse in water, although it was not stated whether any attempts at mechanical homogenization were made. A deviation in following GLP was noted, namely, a data entry was not signed and dated on the day of entry; this deviation did not adversely affect the study results.

DATA EVALUATION REPORT

UICK-2 (p-menthane 3,8 diol)
(Moeller Plus)

STUDY TYPES: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production, and Formulation Process
(OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 26

Primary Reviewer:

Sylvia Milanez, Ph.D., D.A.B.T.

Signature: 

Date: APR 26 1999

Secondary Reviewers:

Robin Brothers, Ph.D., D.A.B.T.

Signature: 

Date: APR 26 1999

Robert H. Ross, M.S., Group Leader

Signature: 

Date: APR 26 1999

Quality Assurance:

Eric B. Lewis, M.S.

Signature: 

Date: APR 26 1999

Disclaimer

This Data Evaluation Report may have been altered by the BPPD subsequent to signing by Oak Ridge National Laboratory personnel.

UICK-2
MRID 44642109

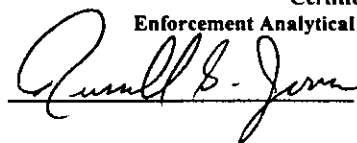
Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production, and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

EPA Reviewer: Russell S. Jones, Ph.D.

EPA Work Assignment Manager:

Sheryl K. Reilly, Ph.D.

Biopesticides & Pollution Prevention Division (7511W)

 Date, 6/29/99
_____, Date, _____

DATA EVALUATION RECORD

STUDY TYPES: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production, and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

DP BARCODE: D252712

SUBMISSION CODE: S555602

P.C. BARCODE: 011550

CASE: 062676

TEST MATERIAL (PURITY): UICK-2 (p-menthane 3,8 diol, 9.82-10.1% a.i.)

SYNONYMS: Uick 2; Moeller Plus (from MRID 44642101)

CITATION: Hildebrandt, D.W. (1998) Product chemistry data for UICK II. Formula number 15045R59-2. S.C. Johnson and Son, Inc., 1525 Howe Street, Racine, WI 53403-2236. Project #00A169, August 21, 1998. MRID 44642109. Unpublished.

SPONSOR: S.C. Johnson & Son, Inc., Product Safety, Toxicology and Environmental Assessment, Mail Station 122, 1525 Howe Street, Racine, Wisconsin 53403-2236.

EXECUTIVE SUMMARY: The product identity and composition, description of starting materials, production process, formation of impurities, certified limits, and enforcement analytical method of UICK-2 are addressed in MRID 44642109. UICK-2 is an end-use product used as an insect repellent on human skin. The UICK-2 active ingredient is p-menthane-3,8-diol (10.100% w/w; 10.00% a.i. accounting for 99% purity, with certified limits of 9.50-10.49% a.i.). UICK-2 inert ingredients consist of

UICK-2 is not manufactured as an integrated system, no chemical reactions are expected to occur or impurities to be formed. Gas chromatography with a flame ionization detector is used to enforce

Manufacturing process information not included.
Inert ingredient information not included.

UICK-2
MRID 44642109

Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production, and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

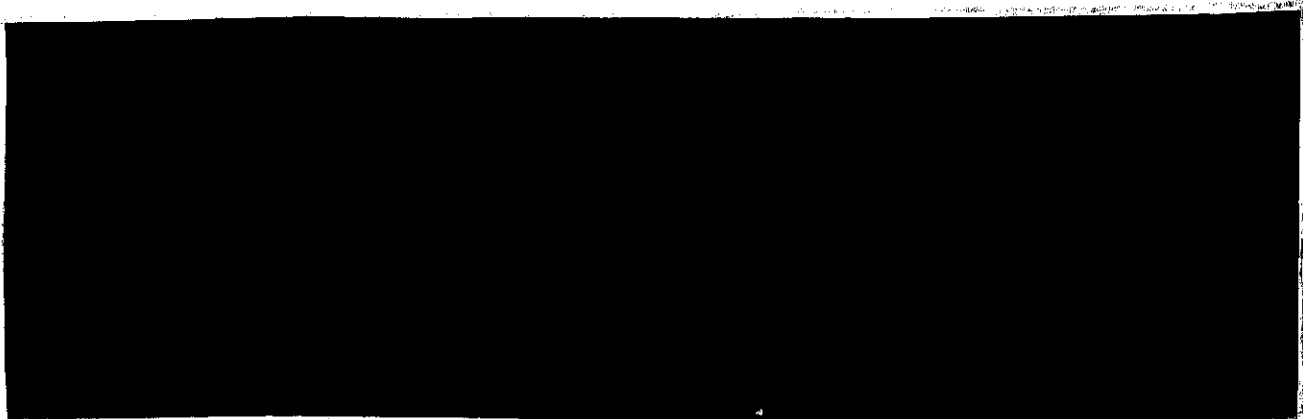
the quantity of p-menthane 3,8-diol in UICK-2.

Classification of the study - **Unacceptable**, but upgradable. The product identity and composition (151-10) data are unacceptable. The percentages by weight of the TGAI and the a.i. listed on the CSF (dated 8/18/98) indicate that the TGAI contains 10% p-menthane-3, 8-diol as its active ingredient. However, the MSD sheet shows that the TGAI contains 93.8% p-menthane-3, 8-diol. This discrepancy must be resolved. Additionally, limits of detection data must be reported for the analytical method.

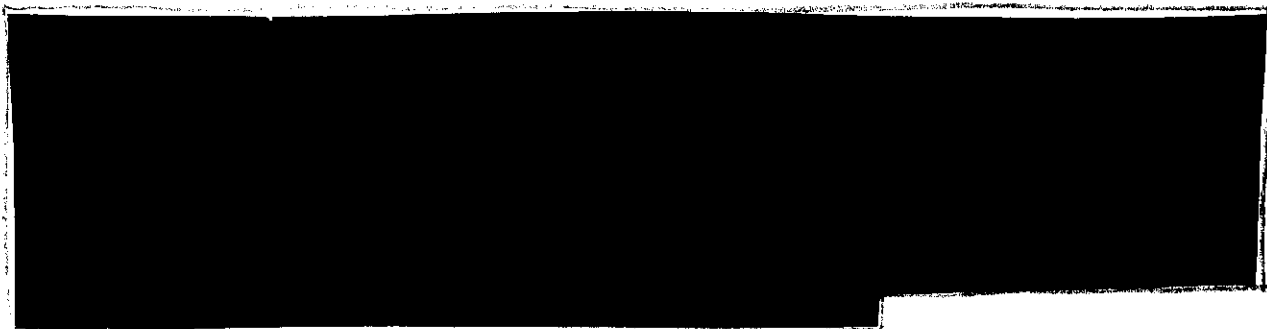
COMPLIANCE: A signed Data Confidentiality statement was provided. The signed GLP compliance statement indicated that GLP Guidelines were not applicable. A Quality Assurance statement was not included.

Inert ingredient information not included.
Manufacturing process information not included.

A. PRODUCT IDENTITY AND COMPOSITION (OPPTS 880.1100)
(Similar to Product Properties Test Guideline OPPTS 830.1550)



B. DESCRIPTION OF STARTING MATERIALS, PRODUCTION, AND FORMULATION PROCESS (OPPTS 880.1200)
(Similar to Product Properties Test Guidelines OPPTS 830.1600 & OPPTS 830.1650)



C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 880.1400)
(Similar to Product Properties Test Guideline OPPTS 830.1670)

UICK-2 is not manufactured as an integrated system and no chemical reactions are required or expected to occur.

D. CERTIFIED LIMITS (OPPTS 830.1750)

The UICK-2 active ingredient is p-menthane 3,8-diol and its lower and upper certified limits in terms of the percent active ingredient are 9.50-10.49%. The limits on a per weight basis should have also been given to be consistent with the other ingredients, of which the certified limits were provided as w/w. UICK-2 inert ingredients consist of

Inert ingredient information not included.

E. ENFORCEMENT ANALYTICAL METHOD (OPPTS 830.1800)

A gas chromatography (GC) method with a flame ionization detector is used to determine the quantity of p-menthane 3,8-diol in liquid insect repellants. Approximately 0.4-0.6 g sample is put into a container (≥ 100 mL), an internal standard is added (10.0 mL of 0.3% dipropyl phthalate), and this is diluted to 100 mL with acetone and mixed thoroughly. One microliter is injected into the GC and analyzed. Acceptable precision and accuracy data were submitted, but limits of detection data were not reported. Limits of detection data are required.

F. DISCUSSION

In MRID 44642109, the product identity and composition, description of starting materials, production process, formation of impurities, certified limits, and enforcement analytical method of UICK-2 were described. UICK-2 is formulated by a batch process involving a simple mixing of the active and inert ingredients, and no chemical reactions are anticipated. Gas chromatography is used as the enforcement analytical method.

The registrant chose to attempt to satisfy several OPPTS Biochemical Test Guidelines [880.1100, (mistakenly given by registrant as 880.1000), 880.1200, 880.1400] and several Product Properties Test Guidelines [OPPTS 830.1750 and 830.1800]. It is unclear to the reviewer why the registrant did not use all Product Properties Test Guidelines, as comparable guidelines were available in all cases.

Classification of studies: **Unacceptable**, but upgradable. The product identity and composition (151-10) data are unacceptable. The percentages by weight of the TGA1 and the a.i. listed on the CSF (dated 8/18/98) indicate that the TGA1 contains 10% p-menthane-3, 8-diol

UICK-2
MRID 44642109

Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production, and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

as its active ingredient. However, the MSD sheet shows that the TGAI contains 93.8% p-menthane-3, 8-diol. This discrepancy must be resolved. Additionally, limits of detection data must be reported for the analytical method.

G. STUDY DEFICIENCIES

The percentages by weight of the TGAI and the a.i. listed on the CSF (dated 8/18/98) indicate that the TGAI contains 10% p-menthane-3, 8-diol as its active ingredient. However, the MSD sheet shows that the TGAI contains 93.8% p-menthane-3, 8-diol. This discrepancy must be resolved. No limits of detection data must be reported for the analytical method.

The OPPTS number for Product Identity and Composition was mistakenly given by the registrant as OPPTS 880.1000, but should have been OPPTS 880.1100.

PC 011550

P-MENTHANE-3,8-DIOL

Page 15 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

☒ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION REPORT

UICK-2 (p-menthane 3,8 diol)
(Moeller Plus)

Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatment
STUDY TYPE: ~~TREATMENTS TO CONTROL PESTS OF HUMANS AND PETS~~
(OPPTS 810.3100)

4

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 26

Primary Reviewer:

Sylvia Milanez, Ph.D., D.A.B.T.

Signature: *Sylvia Milanez*
Date: APR 26 1999

H. Tim Borges, Ph.D., D.A.B.T., MT(ASCP)

Signature: *H.T. Borges*
Date: APR 26 1999

Robert H. Ross, M.S., Group Leader

Signature: *Robert H. Ross*
Date: APR 26 1999

Quality Assurance:

Eric B. Lewis, M.S.

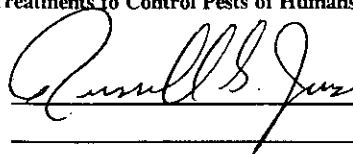
Signature: *Eric B. Lewis*
Date: APR 26 1999

Disclaimer

This Data Evaluation Report may have been altered by the BPPD subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Russell S. Jones
EPA Work Assignment Manager:
Sheryl K. Reilly, Ph.D.
Biopesticides & Pollution Prevention Division (7511C)

 Date, 6/29/99
Date, _____

DATA EVALUATION RECORD

STUDY Type: *Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments, EPA 712-C-98-419, March 1998*. (OPPTS 810.3400)

DP BARCODE: D252712
P.C. BARCODE: 011550

SUBMISSION CODE: S555602
CASE: 062676

TEST MATERIAL (PURITY): UICK-2 (p-menthane 3,8 diol, 9.82-10.1 % a.i.)

SYNONYMS: Uick 2; Moeller Plus (from MRID 44642101)

CITATION: Verwey, R.E. (1998) Determining repellency of Uick 2 (10% p-menthane 3,8 diol) against biting gnats (commonly called no-see-ums) (*Culicoides* spp.), biting flies (black flies) (*Simulium* spp.) and mosquitoes (*Culicidae*) in the field. Entomology Research Center, S.C. Johnson & Son, Inc., 15 Four Mile Rd., Racine, WI 53402. Project number A167, GLP Study 377E1, July 23, 1998 (amendment date). MRID 44642110. Unpublished.

SPONSOR: S.C. Johnson & Son, Inc., Product Safety, Toxicology and Environmental Assessment, Mail Station 122, 1525 Howe Street, Racine, Wisconsin 53403-2236.

EXECUTIVE SUMMARY: In MRID 44642110, the ability of UICK-2 (p-menthane 3,8 diol, 10% a.i., SCJW formula no. 15045R59-2) to repel biting gnats, biting flies, and mosquitoes from human skin was evaluated on the forearms and/or lower legs. Exposure was in a field environment containing continuous biting populations. Efficacy determination was based on the length of time from treatment to the first confirmed bite. Two field tests were conducted for mosquitoes and one each were conducted for biting flies and biting gnats.

Data contained in the submitted studies indicate repellency of up to 5 hours for black flies, up to 2 hours for sand gnats, and for up to 2 hours repellency against mosquitoes. The black fly test was conducted in MI, the sand gnat test was conducted in FL, and the two mosquito tests were respectively conducted in FL and WI. Current guidelines [OPPTS 830.3400, and Subdivision G, 95-10; *Mosquito, Black Fly, Nonbiting Midge, and Biting Midge (Sand Fly) Treatments*] require five field tests for each species at geographically separate locations. New, proposed guidelines will specify that only two field trials are required. Based on the above information, the black fly and sand gnat tests are considered supplemental; to upgrade these studies to acceptable, one additional field test must be submitted for each species at a location that is geographically separated from the first tests.

This study is classified as **Supplemental (guideline)**.

COMPLIANCE: Quality Assurance, Data Confidentiality, and GLP statements were provided. GLP provisions were followed except that the protocol was inadvertently not signed before the test initiation, the test substance stability determination was still in progress, and the weather data were not collected with equipment according to GLP.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material: UICK-2 (p-menthane 3,8 diol, a.i.)

Description: Clear colorless liquid; density given as 0.81 g/mL in MRID 44642101.
Batch/Lot #: SCJW formula no. 15045R59-2
Purity: 10% a.i. (p-menthane 3,8 diol)
Stability: determination in progress
CAS Number: 42822-86-6

2. Vehicle: None noted.

B. STUDY DESIGN and METHODS

1. Locations of trials and identity of pests at test sites

Four field trial test sites were used:

Sand gnats - just west of Yankeetown, FL; 100% *Culicoides mississippiensis*

Black flies - just south of Copper Harbor, MI; 93.3% *Simulium venustum*, 6.7% *Prosimulium mixtum*

Mosquitoes - Kenosha County, WI; 44.0% *Aedes vexans*, 52.0% *Aedes stimulans*, 4.0% *Aedes cinereus*

Mosquitoes - Collier Seminole State Park, FL; 94.6% *Aedes taeniorhynchus*, 2.7% *Aedes infirmatus*, and 2.7% *Mansonia dyari*

2. Field trial dates

Sand gnats (FL) - March 23 and 24, 1998

Black flies (MI) - May 20, 1998

Mosquitoes (WI) - June 15, 1998

Mosquitoes (FL) - March 26 and 27, 1998

3. Test procedure

The forearms (wrist to elbow) and lower legs (knee to ankle) of the test subjects were measured in order to determine how many grams of Uick 2 needed to be applied to achieve 1.0 g/645 cm² of skin surface area. The skin was washed with soap and water and rinsed with alcohol/water. All body areas to which Uick 2 was not to be applied were covered with clothing or a net which was taped at the edges. Uick 2 was applied evenly over the skin using two fingers. The test subjects were exposed to the biting insects in a field environment containing continuous biting populations. The time of each insect bite after Uick 2 application was recorded; this was the protection time. The exposure to the insects was terminated when a second bite was received within 30 minutes of the first bite, at which point the Uick 2 was considered no longer repellent. The subjects were to avoid abrasion or contamination of the treated areas or exertion causing perspiration or body temperature changes.

The landing rates (per minute) of the insects were determined prior to treatment with Uick 2 and, apparently, periodically after treatment (this was not clear from the study report). The test subjects counted the number of insects that landed on each other's front over a 15-second period; this was multiplied by 2 and 4 to get the whole body, 1-minute landing rate. The subjects were to stand motionless during the landing rate counts.

II. RESULTS AND DISCUSSION

A. RESULTS AND DISCUSSION

Field testing with humans was conducted to substantiate the claim that Uick 2 is effective against biting gnats, biting flies, and mosquitoes. To be considered effective, the OPPTS 810.3300 guideline states that a test article should generally provide a minimum of 2-3 hours protection time against mosquitos and 3 hours protection against biting flies. Criteria for sand gnats are not specified in; a 2-3 hour protection time seems reasonable based on the phylogenetic similarity of mosquitoes and sand flies. In the field trials, all of the protection times obtained for black flies were greater than that specified by OPPTS 810.3300. For mosquitoes and gnats, most of the protection times were > 2 hours, and the mean protection time was > 2 hours. Results of the field trials, as summarized in Table 1, indicate that based on the mean protection times, Uick 2 was effective in repelling the insects according to OPPTS 810.3300 guidelines.

TABLE 1. Protection time provided by Uick 2 against a field population of biting insects			
Test species and geographic location	# skin sites tested (number of subjects)	Mean protection time and range (minutes to first bite)	Insect landing rate (# per minute)
Sand gnats (FL)	12 sites (n=3)	158 (69-235)	88-264 (3/23) 56-224 (3/24)
Black flies (MI)	12 sites (n=3)	308 (263-396)	56-184
Mosquitoes (WI)	12 sites (n=3)	167 (49-308)	32-64
Mosquitoes (FL)	12 sites (n=3)	129 (49-237)	56-64 (3/26) 64-120 (3/27)

B. DEFICIENCIES

Only one field trial was conducted for sand gnats and black flies. One additional study must be conducted for each species.